UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA;
STATE OF CALIFORNIA;
STATE OF DELAWARE;
STATE OF FLORIDA;
STATE OF GEORGIA;
STATE OF HAWAII;
STATE OF ILLINOIS;
STATE OF INDIANA;
STATE OF LOUISIANA;
COMMONWEALTH OF MASSACHUSETTS;
STATE OF MICHIGAN;
STATE OF MONTANA;
STATE OF NEVADA;
STATE OF NEW HAMPSHIRE:
STATE OF NEW JERSEY;
STATE OF NEW MEXICO;
STATE OF NEW YORK;
STATE OF OKLAHOMA;
STATE OF RHODE ISLAND;
STATE OF TENNESSEE;
STATE OF TEXAS;
COMMONWEALTH OF VIRGINIA;
STATE OF WISCONSIN;
and the DISTRICT OF COLUMBIA,

EX REL. DAVID MORGAN,

PLAINTIFF/RELATOR,

v.

EXPRESS SCRIPTS, INC.;
CVS CAREMARK CORPORATION;
MEDCO HEALTH SOLUTIONS, INC.;
FIRST DATABANK, INC.; WOLTERS KLUWER HEALTH d/b/a MEDI-SPAN; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; and JOHN DOE CORPORATIONS 1 – 20,

DEFENDANTS.

THIRD AMENDED COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

CIVIL NO.: 05-cv-1714 (HAA)

On behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively the "States and the District of Columbia"), Plaintiff and Relator David Morgan, ("Relator") files this third amended *qui tam* complaint against: Defendants Express Scripts. Inc. ("ESI"), CVS Caremark Corporation ("Caremark"), and Medco Health Solutions, Inc. ("Medco") (the "Pharmacy Benefit Manager Defendants" or "PBM Defendants"); First DataBank, Inc. ("First DataBank" or "FDB"), and Wolters Kluwer Health d/b/a Medi-Span ("Medi-Span") (the "Publisher Defendants" or "Publishers"); McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal"), AmerisourceBergen Corporation ("AmerisourceBergen"), and John Doe Corporations 1 through 20 (the "Wholesaler Defendants" or "Wholesalers") (all collectively "Defendants"); and alleges as follows:

I. SUMMARY OF THE ALLEGATIONS.

1. Relator David Morgan ("Relator") is a licensed pharmacist who for over 15 years has run his own business conducting audits of PBMs for third-party-payor clients.

2. From previous pharmacy auditing experience, Relator understood that the databases published by the two leading providers of drug information services -- First DataBank's National Drug Data File Plus, commonly known as the "Blue Book," and Thomson Medical Economics' The Drug Topics, commonly known as the "Red Book" -- both contained

essentially the same Average Wholesale Price ("AWP") figures.[1] As did many in the drug industry, including government-program administrators, Relator relied on the accuracy of the Blue Book and the Red Book AWP information in conducting audits and reconciling reimbursement claims for his clients.

3. In 2002, while auditing a private third-party payor's pharmacy claims processed by ESI during the preceding seven years, Relator used Red Book to reconcile certain 1999 pharmacy claims. To his surprise, he found that ESI had over-charged his client for drug reimbursements by nearly two percent across the board.

4. Relator learned that ESI had been calculating its reimbursements using Blue Book AWP. Applying AWPs - as reported by the two publications - to his client's claims, Relator discovered that Blue Book's AWP averaged nearly two percent higher.

5. During subsequent PBM audits, Relator compared claims reimbursed based on Blue Book AWP and those reimbursed using Red Book AWP. Relator not only found the same consistent percentage disparity, but found that the overall disparity increased over time. The nearly two percent disparity that he had found in 1999-2001 had increased to 2.6 percent by 2002-03, and to 3.5 percent by 2003-04.

6. Relator then obtained full data sets from both Blue Book and Red Book for a multi-year period. He ran comprehensive analyses, and found that, for brand-name drugs (which represent most of the dollars paid), the Blue Book AWP was approximately four percent higher than Red Book.

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[1] First DataBank's AWP data was distributed electronically to its subscribers and regularly updated, whereas its physical Blue Book was published only once a year. However, because First DataBank's AWP data is commonly known in the industry as Blue Book, "First DataBank" and "Blue Book" are used interchangeably herein and without regard to the medium of particular AWP data.

7. Tellingly, Relator found no such differential for narcotics and other controlled substances, for which prescriptions and dispensing are highly regulated and monitored by the Government.

8. Likewise, Relator found no AWP differential for drugs that were being intensively advertised, such as Viagra and Claritin. However, he observed that once these advertising campaigns wound down or ceased, the same differential appeared.

9. Through his diligence, Relator had thus detected a multi-billion-dollar fraud. As detailed in this Third Amended Complaint, First DataBank (and, for a time, Medi-Span, a subsidiary it later divested), at the urging of wholesaler McKesson, intentionally inflated Blue Book's published AWP over Red Book's numbers, creating an increasingly uniform "spread" between the two.

10. That intentional inflation of Blue Book AWP enabled retailers, wholesalers, and PBMs to profit by causing third-party payors, including the federal and state governments, to reimburse for prescription drugs based on Blue Book AWP.

11. McKesson and First DataBank implemented and perpetrated this fraudulent scheme while publicly representing they maintained an arms-length relationship. First DataBank established and burnished a public reputation for providing the most accurate AWP in its Blue Book. First DataBank represented that it performed sophisticated statistical "surveys" of actual prices being charged by wholesalers in the marketplace, and that it mathematically "weighted" the results of the data obtained from these surveys to arrive at a reasonable empirical value for average wholesale prices in the marketplace.

12. In contrast, the other AWP sources (including Red Book) for the most part relied almost exclusively on suggested wholesale prices or markups reported by the drug manufacturers.

13. Because the federal and state governments (as well as private third-party payors and the public in general) relied on First DataBank's reputation, in many instances the Government required, by contract or even by law, that Blue Book data be used to calculate reimbursements.

14. In reality, First DataBank was not conducting formal mathematical or statistical surveys, and its reputation in the marketplace was wholly undeserved. First DataBank's "surveys" were nothing more than occasional, anecdotal telephone calls to employees of some wholesalers, primarily McKesson. The results were not recorded in writing, and no statistical or mathematical weighting was applied to the data obtained.

15. Moreover, since at least 2000, First DataBank relied almost solely on data provided to it by McKesson. It made no attempt to determine whether the data provided by McKesson represented empirical prices that were charged anywhere in the marketplace by McKesson or any other wholesaler.

16. For its part, McKesson understood that by inflating the "prices" and/or "markups" it provided to First DataBank, it could inflate the payment that its pharmacy customers received from federal and state governments and from other third-party payors, thus boosting their profits substantially. McKesson further understood that because the "prices" and/or "markups" it was reporting to First DataBank reflected neither actual prices nor list prices used in contracts with its customers (and thus had no impact on the actual prices it was charging its customers), McKesson could report whatever prices it wanted to First DataBank in order to influence and increase the

profitability of its customers, without adversely impacting the actual prices it was charging customers or any other aspect of its day-to-day business.

17. Accordingly, McKesson went about systematically inflating AWP on thousands of prescription brand-name drugs by reporting inflated markups and/or prices to First DataBank in order to influence the AWP reported by First DataBank that was relied on by third-party payors. As of the date of the filing of the original complaint in this matter, McKesson and First DataBank had increased the AWPs on over 4,400 brand name prescription drug NDCs, plus thousands of over-the-counter ("OTC") NDCs. Since then, the scheme has not only continued, but in fact expanded and now encompasses nearly 7,000 brand name prescription drug NDCs (*see* Exhibit A attached hereto), even as certain aspects of the scheme have been uncovered and scrutinized.

18. First DataBank, McKesson and the other Wholesaler Defendants knew that as a result of the McKesson and First DataBank scheme, the benchmark used to pay drug claims by third-party payors, including the Government, had materially changed, yet they concealed this fact from their customers and the marketplace and, moreover, exploited it to increase their own profits.

19. While McKesson and First DataBank were carrying out their scheme, the PBM Defendants were exploiting that scheme for their own benefit. The PBM Defendants kept careful track of the pricing of prescription drugs, as it was the very life blood of their business. Very early on, they recognized that Blue Book's reported AWP for many brand name drugs was approximately four percent higher than Red Book's. The PBM Defendants realized that they could exploit this price spread (which they knew was the intended result of a fraudulent scheme) to extract additional profits from their customers, including the federal and state governments.

20. One way that the PBM Defendants capitalized upon the scheme was to place in their third-party payor contracts the right to select Blue Book as the exclusive source for AWPs used to determine reimbursement and/or payment prices. By pricing reimbursements based on Blue Book instead of Red Book, the PBM Defendants could increase their overall prescription revenues by approximately three to four percent. However, to "capture" the spread (rather than allowing the pharmacies, which typically purchased drugs from wholesalers at Wholesale Acquisition Cost ("WAC") plus a certain percentage, to reap the entire spread), the PBM Defendants devised an additional scheme.

21. Under the PBM Defendants' contracts with their government clients, and in their role as Medicare Part D Sponsors and/or subcontractors thereto, reimbursements were typically calculated as a percentage off Blue Book AWP (for example, AWP -11%). At the same time, the PBM Defendants' contracts with pharmacies likewise were calculated as a percentage off AWP, but with a deeper discount (for example, AWP -15%). These deeper discounts (and thus lower reimbursement amounts) were offset because the contracts allowed the pharmacies to keep the full co-pays for any claims that were priced less than the member co-pays, which occurred mostly with generic drugs. By orchestrating this differential, the PBM Defendants profited at the expense of the pharmacies, and, more importantly, at the expense of their government clients who paid for drugs at artificially-inflated prices with taxpayer dollars.

22. The PBM Defendants also contracted with many state Medicaid agencies to serve as their fiscal intermediary to process claims. In this role, the PBM Defendants similarly remained silent as to Blue Book's inflated AWP and exploited the scheme to their pecuniary advantage.

23. In many cases this misconduct violated laws, regulations and/or contracts between the PBM Defendants and the federal and state governments which required prices to be adjusted whenever a material change in market pricing occurred. The PBM Defendants knew that as a result of the McKesson and First DataBank scheme, effective prices had materially changed, yet they concealed this fact from their customers and moreover exploited it to increase their own profits.

24. In short, the Defendant PBMs were in a position to, and had a contractual, fiduciary or other duty to, prevent the damage incurred by the Government as a result of the McKesson and First DataBank scheme, but instead remained silent and exploited the scheme for their own financial benefit.

25. Thus, the inflated and artificial Blue Book AWP caused millions of reimbursement claims to be submitted based on information that McKesson, First DataBank, the PBMs, and other Defendants knew to be false. Accordingly, billions in false claims for prescription drugs were submitted and paid – approximately three percent of all government spending for pharmaceuticals during the years covered by this action. Further, the scheme has continued, and indeed expanded, over time; even as of the date of this Amended Complaint, false claims continue to be filed, and paid, with ever-increasing damage to the Government.

II. THE PARTIES.

26. Relator David Morgan, R. Ph., is a resident of Pennsylvania and has been a licensed pharmacist since 1976. Since 1992, he has been the President of Morgan Healthcare Audits, L.L.C., formerly Morgan Enterprises ("Morgan Healthcare"), located at 3544 N. Progress Avenue, Suite 102, Harrisburg, Pennsylvania 17110. Morgan Healthcare provides contracted consulting and audit services for healthcare-related businesses, private companies,

third party administrators, government agencies (the DOJ, the Food and Drug Administration, the Pennsylvania Attorney General's Office--Bureau of Narcotics Investigations and Medicaid Fraud Control Section, and the Pennsylvania Department of Welfare--Bureau of Program Integrity), and law enforcement agencies (the Federal Bureau of Investigation and the Drug Enforcement Administration).

27. Relator brings this action on behalf of himself and the United States pursuant to the FCA, and on behalf of himself and the Plaintiff States and the District of Columbia pursuant to their respective false claims acts. Relator has personal and direct knowledge of the violations and allegations set forth herein.

28. Relator acquired personal knowledge of the Defendants' unlawful practices as a result of auditing millions of pharmacy claims of several major PBMs on behalf of his private third-party payor clients, using published Red Book and Blue Book data. These PBMs included ESI, Medco, Caremark, and AdvancePCS (now merged into Caremark), and the claims Relator audited covered the period 1995-2005. Relator voluntarily provided to the Government substantially all of the information in his possession prior to the original filing of this lawsuit.

29. Relator is not aware of any "public disclosure" in connection with the false claims alleged in this Complaint as defined in 31 U.S.C. § 3730(e)(4)(A) and in the false claims acts of the Plaintiff States and the District of Columbia. In any event, this Court has jurisdiction, because Relator is an "original source" under the Acts because he has knowledge which is both direct and independent of any public disclosures to the extent they may exist.

30. Defendant ESI is a Delaware corporation with its principal place of business at One Express Way, St. Louis, Missouri, 63121. ESI is one of the nation's leading providers of

comprehensive prescription drug benefit programs. In 2003, ESI managed more than 400 million prescriptions with sales in excess of $13 billion.

31. Defendant Caremark was formed on March 22, 2007 by the merger of CVS, a Delaware corporation with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island, 02895, with the previously-named Defendant Caremark Rx, a Delaware corporation with its principal place of business located in Nashville, Tennessee. In March 2005, Caremark acquired rival Advance PCS. Caremark is one of the nation's leading providers of comprehensive prescription drug benefit programs. In 2007, Caremark provided services to over 2,000 health plans, administering hundreds of millions of prescription claims through a network of over 60,000 participating pharmacies, and generated over $43 billion in revenue, including over $4.6 billion in retail copayments.

32. Defendant Medco, successor-in-interest to Merck-Medco Managed Care, L.L.C., is a Delaware corporation with its principal place of business located at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417. Medco is the nation's leading provider of comprehensive prescription drug benefit programs. In 2007, Medco managed more than 560 million prescriptions with sales in excess of $44 billion. Medco operates through a network of over 60,000 retail pharmacies, as well as highly automated mail-order fulfillment centers through which, pursuant to contracts with the federal government, it fills tens of thousands of prescriptions for persons covered by FEHBP and other federally-funded health care programs.

33. Defendant First DataBank, with a principal place of business at 1111 Bayhill Drive, San Bruno, California 94066, produces and sells integratable drug data files primarily in the United States, and also provides design and publishing services to retail pharmacies for products such as drug information brochures distributed to patients. First DataBank supplies

data to drug wholesalers, more than 40,000 pharmacies, 4,000 hospitals, all 50 state Medicaid programs, and most major national vendor and private drug benefit programs. The firm also has offices in Indianapolis, Indiana, St. Louis, Missouri and Exeter, England. Its self-reported revenue for 2006 was approximately $26 million.

34. Defendant Medi-Span also produces and sells integratable drug data files primarily in the United States, with its principal place of business located at 161 West Washington Street, Conshohocken, Pennsylvania 19428. From 1998, First DataBank owned Medi-Span and its MDDB database until it was required in December 2001 by the Federal Trade Commission to divest its interest in Medi-Span to Facts & Comparisons, a division of Wolters Kluwer Health's Clinical Solutions unit, which divestiture was consummated on January 5, 2002. Wolters Kluwer Health is a division of Wolters Kluwer NV, a leading multinational publisher headquartered in Amsterdam, The Netherlands. In January 2002 it was publicly disclosed that Medi-Span had annual sales of approximately $26 million through its publication of electronic drug data.

35. Defendant McKesson is a Delaware corporation founded in 1833, with its principal place of business located at 1 Post Street, San Francisco, California 94104. McKesson has long been one of the nation's largest drug wholesalers, and for over 25 years, beginning in 1968, McKesson also owned the largest PBM in the nation, PCS. In 1994 McKesson sold PCS to the PBM competitor Advance Paradigm, which was renamed Advance PCS until its acquisition by Caremark in March 2004. Thereafter, McKesson developed a division to provide data services to its retail clients, which division has a higher profit margin than its wholesale drug division. McKesson was ranked 18th on the 2008 Fortune 500 list, based on 2007 revenues

of $93.6 billion, and is the nation's largest health care services company. McKesson reported $101.7 billion in revenue for the fiscal year ending March 31, 2008.

36. Defendant Cardinal is an Ohio corporation with its principal place of business at 7000 Cardinal Place, Dublin, Ohio 43017. Formed in 1979, Cardinal's Pharmaceutical Distribution and Provider Services segment is one of this country's leading wholesale distributors of a broad line of pharmaceutical and other health care products. In 2001 Cardinal acquired Bindley Western Industries, Inc., another leading wholesale distributor of pharmaceuticals. For fiscal year ending June 30, 2007, Cardinal reported $87 billion in revenue. Its 2007 total corporate revenue of $88.3 billion earned it the 19th ranking on the 2008 Fortune 500 list.

37. Defendant AmerisourceBergen is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Suite 100, Chesterbrook, Pennsylvania 19087. AmerisourceBergen is a leading wholesale distributor of pharmaceutical products and related health care services that was formed in 2001 by the merger of AmeriSource Health Corporation and Bergen Brunswig Corporation, the third largest distributor of pharmaceuticals and related healthcare products. For 2007, AmerisourceBergen reported $66.1 billion in revenue and was ranked 28th on the 2008 Fortune 500 list.

38. Defendants John Doe Corporations 1 through 20 are wholesale distributors in the United States pharmaceutical market.

III. JURISDICTION, VENUE AND SPECIAL FILING REQUIREMENTS.

39. This Court has original jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. § 1331 on the grounds that it arises under the laws of the United States, specifically the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and because the amount in

controversy clearly exceeds $75,000.

40. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the various States and the District of Columbia on the grounds that such claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

41. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and the Defendants have sufficient minimum contacts with the United States of America.

42. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because the acts complained of herein occurred in the State of New Jersey within this judicial district.

43. In accordance with 31 U.S.C. § 3730(b)(2), the Third Amended Complaint will be filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on the Defendants until the Court so orders.

44. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator has provided the Government with a copy of the Third Amended Complaint and/or a written disclosure of substantially all material evidence and material information in its possession contemporaneous with the filing of the Third Amended Complaint. Relator has complied with this provision by, *inter alia*, serving copies of the original Complaint and this Third Amended Complaint on Christopher Christie, United States Attorney for the District of New Jersey and the Honorable Michael Mukaskey, United States Attorney General, or their successors.

IV. GOVERNING LAWS.

A. The Federal False Claims Act.

45. Originally enacted in 1863, the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.*, was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

46. 31 U.S.C. § 3729(a)(1) & (2) imposes liability upon any person who: "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval;" or "knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved." Any person found to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a).

47. Significantly, the False Claims Act imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

48. The False Claims Act also broadly defines a "claim" as one that "includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c).

49. The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene and take over primary responsibility for prosecuting the action.

B. State False Claims Acts.

50. This action is also filed on behalf of several states with False Claims Acts which closely track the Federal FCA: the California False Claims Act, Cal. Govt. Code §§ 12650, *et seq.*; the Delaware False Claims and False Reporting Act, 6 Del. Code Ann. §§ 1201, *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081, *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code. Ann. §§ 49-4-168.1 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1, *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5A, *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*; the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§ 357.010, *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b; the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1, *et seq.*; the New York False Claims Act, N.Y. Fin. Law §§ 187, *et seq.*; the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. Ann. §§ 5053 *et seq.*; The State False Claims Act (Rhode Island), R.I. Gen. Laws §§ 9-1.1-

1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001, *et seq.*, the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1, *et seq.*; the Wisconsin False Claims for Medical Assistance Law, Wisc. Stat. § 20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§ 2-308.03, *et seq.*

C. Federal Government-funded Health Insurance Plans.

1. TRICARE/CHAMPVA.

51. TRICARE, administered by the Department of Defense ("DoD"), is the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents.

52. TRICARE operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Multiple managed care support contractors create networks of civilian health care providers. Prescription drug benefits are provided through TRICARE Pharmacy Program Services through which members can have prescriptions filled at: military treatment facility pharmacies; the TRICARE Mail Order Pharmacy; TRICARE retail network pharmacies; and non-network pharmacies.

53. Similarly, CHAMPVA, administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage to qualified families of deceased or 100% disabled

veterans.

54. In 2006, the military spent approximately $6.2 billion on pharmacy benefits. In 2003, ESI was awarded the contract to provide mail and retail pharmacy services to the DoD. In February 2008, McKesson was awarded a one-year contract worth up to $821 million to supply pharmaceuticals to TRICARE.

2. Federal Employees Health Benefits Plan ("FEHBP").

55. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. The Office of Personnel Management manages FEHBP plans that collectively pay more than $2 billion annually in prescription drug benefits.

D. Federal Government-funded Assistance Programs.

1. Medicare.

56. Medicare is a federal government-funded health assistance program primarily benefiting the elderly that was created in 1965 when Title XVIII of the Social Security Act was adopted.

57. Medicare Part B covers the costs of some prescription drugs that are administered by physicians. Under this program, Medicare reimburses up to 80 percent of the allowable costs of those drugs with the other 20 percent being paid by the patient, the Medicare beneficiary. Medicare calculates the "allowable amount" (*i.e.*, the amount that Medicare will pay) based upon the payment methodology set forth in 42 C.F.R. § 405.517.

58. The Balanced Budget Act of 1997 adjusted Medicare Part B drug reimbursement rates to the "lower of the actual charge on the Medicare claim for benefits or 95 percent of the

national average price of the drug," down from 100 percent. In December 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 adjusted the formula effective January 1, 2004, to "the lower of the actual charge on the Medicare Claim for benefits or 85% of the national average price of the drug." Some companies obtained limited relief from strict application of AWP-15%, or reimbursement of only 85% of the cost of the drugs. In addition, some products, such as renal dialysis products and blood clotting factors, were exempt from the charge and continued to be reimbursed at AWP-5%, or 95% of the cost.

59. Effective January 1, 2005, the Medicare Prescription Drug, Improvement, and Modernization Act changed the Medicare reimbursement to a formula based upon 106 percent of the manufacturer's calculation of the Average Sales Price ("ASP") for each drug. 42 U.S.C. § 1395w-3(a) and (b). The manufacturers are to report ASP directly to the Government on a quarterly basis. The ASP is to reflect "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than those under section 1396r-8)." 42 U.S.C. § 1395w3a(c). This is similar to the pre-existing requirement that manufacturers report their "best price" to Medicaid, but without the additional obligation to pay rebates to the assistance program based on that price. *See* 42 U.S.C. § 1396r-8. Upon information and belief, based upon Relator's audit of prescription drug claims, Medicare Part B has not implemented this change and continues to pay for prescription drugs based on a percentage of AWP.

60. Although Medicare traditionally did not cover outpatient prescription drugs, effective January 1, 2006, and as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare Part D provides for a Voluntary Prescription Drug Benefit Program. Under Medicare Part D, the reimbursement rates for prescription drugs are not set by

statute, setting up instead a free-market structure of Part D sponsors whose competition was supposed to result in the lowest possible drug costs.

2. Medicaid.

61. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program for the medically needy aged, blind, disabled and families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid Program is funded by both Federal and State monies, collectively referred to as Medicaid Funds, with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b, 1396d(b).

62. Under the Medicaid program, federal regulations require that each State's reimbursement for a drug not exceed, in the aggregate, the lower of its estimated acquisition costs or the providers' usual and customary ("U&C") charge to the public for that drug. State Medicaid agencies typically estimate acquisition costs by discounting the drug's AWP from 4 to 17 percent. *See* 42 U.S.C. §1396r-8(c)(1)(c)(ii).

GENERAL FACTUAL ALLEGATIONS

I. THE PHARMACEUTICAL INDUSTRY AND THE DETERMINATION OF AWP.

63. The sale of pharmaceuticals in the United States is a vast industry measured in the hundreds of billions of dollars. It encompasses thousands of prescription and over-the-counter medications in their various forms, including intravenous solutions, inhalation solutions, oral tablets and liquids, and topical applications.

64. Major players in the distribution of drugs include manufacturers, middlemen such as wholesalers, and retailers, which include pharmacies that fill prescriptions and healthcare providers that administer drugs directly to patients. The wholesalers typically buy the drugs in

bulk and then add value by providing repackaging, labeling, and data services to retail pharmacy clients.

65. Under most health-insurance plans, retail pharmacies and medical providers are usually reimbursed by third-party payors, along with a co-payment by the patient. Because of the complexity of managing the prescription drug portion of such coverage, most third-party payors, including government agencies, contracted with a PBM to administer the drug benefit portion of coverage, including payment to the pharmacies or medical providers. PBMs handle prescription claims for over 70% of the covered population, comprising over 80% of the retail prescription drug spending in the United States.

66. In the United States, state and federal government spending on drugs exceeds $100 billion annually. In 2006, Medicare Part D began coverage for outpatient drugs, which resulted in overall Medicare spending increasing by $63.3 billion, to $401.3 billion. At the same time, Medicaid spending, which already included broad outpatient prescription drug coverage, remained nearly steady at $310.6 billion.

67. Because the pharmaceutical industry involves thousands of players, a need arose to standardize the prices third-party payors (including the Government) would pay for drugs. Independent drug information services ("publishers"), among them First DataBank, filled this need by periodically publishing comprehensive lists (and later, electronic databases) of wholesale prices for drugs in the marketplace. Purportedly employing various methods of data collection and analysis, the publishers reported amounts they denoted to be the "average" wholesale price for each drug. Over time, by common understanding, usage and practice in the industry, the AWP reported by these independent publishers became the touchstone upon which third-party payors began, and have continued, to determine the allowable coverage payment for

prescription drugs. Because First DataBank purported to employ a more sophisticated method of collecting and analyzing pricing data, it became the primary source of AWP for many third-party payors.

68. For every variation of each drug's chemical identity, dosage form, manufacturer, strength, and package size, a unique National Drug Code ("NDC") number is assigned (by the manufacturer, or where drugs are repackaged, by the wholesaler or retailer), which is required by law to be filed with the Food and Drug Administration ("FDA") for recording in a national drug database.

69. A 2006 government investigation found that the national drug database of NDCs had not been properly maintained. Thousands of NDCs were not reported to the FDA and instead resided solely in the databases of drug data publishers such as First DataBank, making publishers' services indispensible to the industry. Moreover, this situation allowed First DataBank to change the NDC numbers assigned to drugs when it saw fit, such as to avoid detection of its AWP manipulations.

II. MCKESSON AND FIRST DATABANK'S SCHEME TO RAISE AWP.

A. Setting the Stage.

1. DOJ/NAMFCU Engage the FDB to Remedy the AWP for 51 Drugs Covered by Medicare.

70. In late 1999 and early 2000, the Department of Justice ("DOJ"), the Department of Health and Human Services ("HHS"), the Department of Health and Human Services Office of the Inspector General ("OIG"), and the National Association of Medicaid Fraud Control Units ("NAMFCU") investigated how AWP was determined for 51 physician-administered injectable or inhalation drugs covered by Medicare and Medicaid. Those drugs comprised only 400 out of over 10,000 NDCs. The investigation concluded that the drug manufacturers were reporting

average wholesale prices for those drugs that were higher than the actual prices charged by wholesalers. The investigation did not, however, fully explore the methodologies the publishers had applied to arrive at those fictitious values, or the wholesalers' pricing practices. Because AWP was the benchmark for reimbursement under Medicare and Medicaid, NAMFCU concluded that the inflated AWP "made Medicaid and Medicare substantially overpay for specific drug products." NAMFCU Public Bulletin, *Notification of Adjustments to Average Wholesale Price On Selected NDCS*, PB-00-50 (July 2000.)

71. In an effort to remedy the situation as to those investigated drugs, DOJ, HHS, OIG and NAMFCU undertook a project to set a more accurate pricing schedule that would reflect actual average wholesale prices. These agencies represented to state Medicaid agencies that the project would be a comprehensive effort, with repricing of the 400 NDCs investigated being only the first phase. (*See, e.g.*, February 16, 2000 letter by NAMFCU Drug Pricing Team to Pharmacy Director, State of West Virginia; Utah State Medicaid DUR Committee, *The Amber Sheet*, Vol. 8, No. 4, July 2000.)

72. Building on the substance of a proposal presented to State Pharmacy Directors in July 1999 by DOJ, OIG and certain state MFCU representatives, NAMFCU (and/or representatives of state MFCUs) met with First DataBank to develop "procedures that will improve the accuracy and validity of the information provided to the States." NAMFCU, believing it had reached an agreement with First DataBank, announced the new procedures in a letter to interested parties, including state Medicaid officials.

> Stated briefly, under the impending change to current procedures, FDB will base the average wholesale prices it reports on **market prices**, rather than the prices identified by manufacturers . . . This revised procedure does not change the terms of the company's [First DataBank's] contract with your State, but merely provides an **improved means for First DataBank to provide more accurate information to the States**. More importantly, in view of the Medicaid programs'

> legal obligation to reimburse true provider acquisition costs, **such an effort by the States to ensure that payment is based on actual prices is mandatory.** Consequently, no current legal commitment or program regulations are being altered. On the contrary, it is the goal of the revised reporting process to ensure compliance with *existing* laws and contracts.

(February 16, 2000 letter by NAMFCU Drug Pricing Team to Pharmacy Director, State of West Virginia (emphasis added).)

73. NAMFCU explained the new procedures as part of a comprehensive effort: "[U]ltimately, it is our intention that continuation of our inquiry will result in fundamental changes regarding the reporting of pharmaceutical prices and a consequent reduction in the cost of drugs to government health care programs." (*Id.*). The letter also emphasized that the shift to basing AWP on market prices "will result in a significant reduction in reimbursement for the affected drugs." (*Id.*)

74. For its part, First DataBank agreed that: (1) it would use data that DOJ and NAMFCU had collected concerning the investigated drugs to calculate and publish a new AWP for those drugs that would be "adjusted downward," and (2) it would update "the AWP of these NDCs every six months based on a survey of specific wholesalers by First DataBank." Those specific wholesalers included defendants McKesson and Bergen Brunswig (later merged with AmeriSource), along with a few specialty wholesalers. A handful of Group Purchasing Organizations ("GPOs") were also enlisted by the authorities to assist. (*See, e.g.*, Utah State Medicaid DUR Committee, *The Amber Sheet,* Vol. 8, No. 4, July 2000).

75. Further, First DataBank agreed to "cooperat[e] with representatives of several states' Medicaid Fraud Control Units in correcting the erroneously high AWPs through a new survey mechanism for obtaining AWP information." (*Notification of Adjustment to Average Wholesale Price on Selected NDCs,* Connecticut Medicaid PB-00-50, July 2000.)

76. Since most state Medical Assistance Programs "rel[ied] on AWP data in calculating allowable reimbursement for dispensed medications covered by the programs," NAMFCU determined that First DataBank's representations were material and advised all Medicaid pharmacists of these representations. (*Id.*) In reliance on First DataBank's representations, states continued using and/or switched to First DataBank as the source of AWP data to be used in calculating allowable reimbursements.

77. The prospect of downward-adjusted AWPs for the investigated drugs was not welcomed by retail pharmacies. The pharmacies complained that NAMFCU had unilaterally reduced the AWP on those drugs and thereby interfered with reimbursements based on First DataBank's determination of AWP. One manufacturer sought to enjoin the NAMFCU's efforts, asserting that only the state Medicaid agencies, rather than NAMFCU, had the authority to establish methods and procedures to determine prescription drug coverage levels under Medicaid. *Alpha Therapeutic Corporation v. Terry,* No. 1:00-cv-01947 (D.D.C. filed August 11, 2000) (dismissed August 5, 2002 on jurisdictional grounds.)

78. In addition, pharmacy groups, such as the National Association of Retail Druggists ("NARD"), the National Community Pharmacists Association ("NCPA"), and the National Association of Chain Drug Stores ("NACDS"), engaged in substantial lobbying of Congress. These efforts resulted in Medicaid dropping its demand that the new starting AWP for those drugs had to be the downward-adjusted prices determined by NAMFCU. Nonetheless, NAMFCU, state Medicaid agencies, and the federal government understood that First DataBank remained committed to publishing AWPs that would be based on "a new survey mechanism for obtaining AWP information." (*Notification of Adjustment to Average Wholesale Price on Selected NDCs,* Connecticut Medicaid PB-00-50, July 2000.)

79. Following this commitment to remedy its pricing methodology, in March 2000, First DataBank represented that its published AWP was the "average of the *prices charged* by the national wholesalers for a given product (NDC)" based on "surveys [of] national wholesalers to ascertain what the price is" and maintained this definition for the next few years. (First DataBank, *Price Alert: The Official Guide to AWP Pricing* March 15, 2000, ("2000 Price Alert") (emphasis added).)

2. First DataBank Misleads DOJ, HHS, OIG and NAMFCU About the Method it Uses to Determine AWP.

80. DOJ, HHS, OIG, NAMFCU, and each State's Medicaid Agency and MFCU relied on the integrity of First DataBank's representations that it had the expertise and the intention to generate AWPs that would reflect the real prices retailers paid for the drugs. Those entities also relied upon McKesson and AmerisourceBergen's representations and commitments to provide First DataBank with accurate retail pricing data.

81. Specifically, NAMFCU and each state's Medicaid Agency and MFCU relied on First DataBank's representation that it would not rely solely upon the manufacturer's reported prices and instead would perform its own reliable, statistically valid surveys of wholesalers to collect empirical data about prices "charged" in the marketplace. First DataBank further represented that it would then input the survey data into valid mathematical formulas that would generate an actual weighted average of the price retailers were paying in the marketplace. (Department of Health and Human Services, Office of the Inspector General, *Medicaid's Use of Revised Average Wholesale Prices,* at p. 3, OEI-03-01-00010, September 2001.) Importantly, these representations necessarily implied that First DataBank's new AWPs would be *lower* than the artificial AWPs based on the manufacturers' suggested markup (which Red Book continued to publish). Thus, First DataBank led NAMFCU (and the federal and state government

Plaintiffs) to believe that the use of the revised mechanism would result in a significant *reduction* in drug reimbursement costs. (*Id.*)

82. Contemporaneously, First DataBank made these same representations to the industry, third-party payors, and the general public in its March 15, 2000 Price Alert, which clarified earlier statements as to how it arrived at AWP dating to at least 1991.

83. The March 15, 2000 Price Alert also further explained that manufacturers did not set AWP and that First DataBank would report the manufacturer's SWP as a "different data element on the NDDF file." The publication then stated that First DataBank was "having more instances where [the SWP and AWP] are different," and that, "[w]e will populate the SWP with the new markup, but will survey the national wholesalers to determine AWP. The AWP will be populated with the wholesaler survey price even if it disagrees with the SWP." (FDB NJ/DOJ 00269-72, at 71.) These statements further emphasized that First DataBank's AWP reflected an average of actual prices paid by retailers.

84. In reliance on First DataBank's representations that its methodology would create more accurate, lower AWPs that would save the Government money, state and federal governments decided to switch to, or continue to use, First DataBank's published AWP as the benchmark for calculating reimbursements under Medicaid and Medicare.

85. At various times, First DataBank also knowingly made the following false public statements about its Blue Book and the underlying methodology of its published AWPs, which further led governmental agencies and other third-party payors to rely on their validity:

a. Blue Book is "[o]ne of the industry's most trusted and widely used sources of up-to-date drug information," implying that Blue Book data, including AWP, were current and accurate;

b. Blue Book "[s]ets the standard in the health care industry of description, pricing and clinical information on drugs," suggesting that Blue Book's pricing data were the highest quality and accuracy in the industry;

c. In contrast to Red Book, which published the manufacturers' suggested AWP, Blue Book "surveyed full-line national wholesalers" (http://www.firstdatabank.com/customer_support/drug_pricing_policy/ as of June 3, 2005), and calculated the AWP based on a weighted average, not a consensus average, implying that First DataBank collected pricing data from most if not all of the "full-line national wholesalers," and performed calculations that took into account each wholesaler's markup and other factors. (First DataBank, *Monthly Interest,* Vol. 6, No. 9, September 1991, FDB NJ/DOJ 000256-58, at 57; First DataBank, *Price Alert,* Vol. 11, No. 6, June 15, 1999; First DataBank, *Price Alert,* March 15, 2000, FDB NJ/DOJ 00269-72, at 71); http://www.firstdatabank.com/customer_support/faqs/ as of December 12, 2002.)

d. "[T]he number of surveys performed is increasing," suggesting that First DataBank was expanding the universe of actual pricing data and thus publishing AWPs that more accurately reflected actual market prices (First DataBank, *Monthly Interest,* Vol. 6, No. 9, September 1991, FDB NJ/DOJ 000256-58, at 57; First DataBank, *Price Alert,* Vol. 11, No. 6, June 15, 1999; First DataBank, *Price Alert,* March 15, 2000, FDB NJ/DOJ 00269-72, at 71); http://www.firstdatabank.com/customer_support/faqs/ as of December 12, 2002).

e. First DataBank compiled a "weighted average" of the wholesalers' markups, implying that it obtained the wholesalers' actual pricing relative to WAC, *i.e.*,

First DataBank would not need to calculate an average if it only obtained from each wholesaler the identical markup over WAC suggested by the manufacturers (First DataBank, *Monthly Interest,* Vol. 6, No. 9, September 1991, FDB NJ/DOJ 000256-58, at 57; First DataBank, *Price Alert,* Vol. 11, No. 6, June 15, 1999; First DataBank, *Price Alert,* March 15, 2000, FDB NJ/DOJ 00269-72, at 71); http://www.firstdatabank.com/customer_support/faqs/ as of December 12, 2002); and

f. Representing that First DataBank surveyed drug wholesalers that represented two-thirds of the market. (First DataBank, *Monthly Interest,* Vol. 6, No. 9, September 1991, FDB NJ/DOJ 000256-58, at 57; First DataBank, *Price Alert,* Vol. 11, No. 6, June 15, 1999; First DataBank, *Price Alert,* March 15, 2000, FDB NJ/DOJ 00269-72, at 71; http://www.firstdatabank.com/customer_support/faqs/ as of December 12, 2002.)

86. The federal and state governments relied on First DataBank's statements and commitments during the NAMFCU investigation. For example, in a subsequent assessment, OIG emphasized NAMFCU's strong recommendation to use and rely on FDB as the most accurate source for AWP, quoting NAMFCU's February 2000 letter to the Medicaid Pharmacists for each of the states and the District of Columbia:

> [T]his revised procedure provides an improved means for First DataBank to provide more accurate information to the State. More importantly, in view of the Medicaid program's legal obligation to reimburse true provider acquisition costs, *such an effort by the States to ensure that payment is based on actual prices is mandatory.*

(*Medicaid's Use of Revised Average Wholesale Prices (OEI-03-01-00010)*, OIG, September 2001 ("2001 OIG Report") (emphasis added); available at http://oig.hhs.gov/oei/reports/oei-03-01-00010.pdf (last visited July 8, 2008.)

87. As a result of the NAMFCU investigation, First DataBank, McKesson, and AmerisourceBergen were undeniably aware that when the state and federal governments paid for prescription drugs they would be relying upon wholesalers (including McKesson and AmerisourceBergen) to accurately report to First DataBank the prices at which they were selling drugs to retailers. Likewise, the governments would be relying upon First DataBank to perform empirical "surveys," to apply a market-share weighting, and to publish AWPs that accurately reflected the weighted average of the actual prices charged.

88. Given their knowledge of the state and federal governments' reliance on their pricing information, the ensuing conduct of First DataBank, McKesson and AmerisourceBergen constituted knowingly making or using, or causing to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the government, and/or caused false or fraudulent claims to be presented for payment or approval, all in violation of state and federal false claims acts.

89. Specifically, McKesson and AmerisourceBergen knowingly made or used false statements when they provided First DataBank with false, inflated prices and/or fictitious markups over WAC instead of actual net prices or actual effective markups or markdowns to WAC at which they sold drugs to retailers.

90. Furthermore, McKesson and AmerisourceBergen knowingly caused false statements to be made or used by First DataBank because they intended and knew that First DataBank would use the fictitious pricing information to determine and publish false AWPs, and

intended and knew that these false AWPs would be relied upon by the Government to determine Government reimbursements and ultimately cause the Government to pay more than it would have paid but for this scheme.

91. In addition, by and through their acts and omissions, McKesson and AmerisourceBergen knowingly caused false or fraudulent claims to be presented to state and federal governments for payment or approval.

92. For its part, First DataBank knew, based on the investigation by DOJ, HHS, OIG and NAMFCU, that any pricing data from wholesalers that reflected a markup over WAC greater than approximately 5% was fictitious and did not reflect actual sale prices. Thus, when First DataBank received such pricing data from McKesson and AmerisourceBergen, and then used that data to determine and publish its AWP, as it claimed to be doing, it knowingly used false records or statements, knowingly made its own false records or statements, and knowingly caused these false records or statements to ultimately be used to get false or fraudulent claims paid or approved. First DataBank did so with the knowledge that the claims for coverage would be submitted to and paid by the Government relying upon the inflated AWP created by the false information and ultimately cause the Government to pay more than it should have pursuant to this scheme.

93. In addition, by and through its acts and omissions, First DataBank knowingly caused false or fraudulent claims to be presented to state and federal governments for payment or approval.